DEPARTMENT OF THE ARMY
MEDICAL DEPARTMENT ACTIVITY
Fort Huachuca, Arizona 85613-7079

MEDDAC Memorandum 10 August 2006
No. 40-154

Medical Service
SAFE MEDICAL DEVICES ACT (SMDA)

1. HISTORY. This issue publishes a revision of this publication.

2. PURPOSE. This memorandum establishes responsibilities and outlines procedures for implementation of the Safe Medical Devices Act (SMDA) of 1990

3. SCOPE. This memorandum is applicable to all areas within USA Medical Department Activity (MEDDAC).

4. REFERENCES.

4.1 MEDDAC Memorandum 750-2, Repair and Service of Medical and Dental Equipment.

4.2 Safe Medical Devices Act (SMDA) of 1990.

4.3 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et. seq., as amended.

4.4 Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Ambulatory Version, Comprehensive Accreditation Manual.

4.5 AR 40-68, Quality Assurance Administration

5. GENERAL. The SMDA of 1990 imposes two requirements:

5.1 Medical Device Reporting under the SMDA became effective in all Department of Defense (DoD) Medical Treatment Facilities (MTF) on 28 Nov 91. This requires the reporting of information, which reasonably suggests that a device has or may have caused the death of, serious illness of, or serious injury to a patient. See paragraph 7.1 for procedures for reporting.

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* This memorandum supersedes MEDDAC Memo 40-154,dated 21 Feb 2005

5.2 Medical Device Tracking - Medical device tracking under the SMDA became effective on 29 Aug 93. The goal of tracking is to ensure that the Food and Drug Administration (FDA) can require manufacturers to expeditiously remove potentially dangerous or defective devices from the market and/or notify patients of significant device problems. The FDA may use its discretionary authority to designate and require tracking of additional devices if it considers a device to be potentially unsafe. Changes will be distributed to appropriate personnel when received. Questions about devices to be tracked should be addressed to the MTF Risk Manager. Devices to be tracked as of 29 Aug 93 are:

5.2.1 Permanently implantable device where failure would likely result in serious adverse health consequences:

5.2.1.1 Vascular graft prosthesis of less than 6 millimeters diameter.

5.2.1.2 Vascular graft prosthesis of 6 millimeters and greater diameter.

5.2.1.3 Ventricular bypass (assist) device.

5.2.1.4 Implantable pacemaker pulse generator.

5.2.1.5 Cardiovascular permanent pacemaker electrode.

5.2.1.6 Annuloplasty ring.

5.2.1.7 Replacement heart valve.

5.2.1.8 Automatic implantable cardioverter/defibrillator.

5.2.1.9 Tracheal prosthesis.

5.2.1.10 Implanted cerebellar stimulator.

5.2.1.11 Implanted diaphragmatic/phrenic nerve stimulator.

5.2.1.12 Implantable infusion pumps.

5.2.1.13 Total temporomandibular joint (TMJ) prosthesis

5.2.1.14 Glenoid fossa prosthesis.

5.2.1.15 Mandibular condyle prosthesis.

5.2.1.16 Interarticular disk prosthesis (interpositional implant).

5.2.2 Life-sustaining or life-supporting devices used outside the facility whose failure would be reasonably likely to have serious adverse health consequences:

5.2.2.1 Breathing frequency monitor (apnea monitor) including ventilatory efforts.

5.2.2.2 Continuous ventilator.

5.2.2.3 DC-defibrillator and paddles.

5.2.3 FDA-designated devices:

5.2.3.1 Penile inflatable implant.

5.2.3.2 Silicone inflatable breast prosthesis.

5.2.3.3 Silicone gel-filled breast prosthesis.

5.2.3.4 Silicone gel-filled testicular prosthesis.

5.2.3.5 Silicone gel-filled chin prosthesis.

5.2.3.6 Silicone gel-filled Angelchik reflux valve.

5.2.3.7 Infusion pumps (electro mechanical only).

6. RESPONSIBILITY.

6.1 The Commander is responsible for establishing and maintaining a program, which ensures compliance with the SMDA, and appointing a designated person to coordinate the program for the facility.

6.2 The Chief, Clinical Engineering ensures that tracking and reporting requirements of this memorandum and the SMDA are properly carried out in all clinical areas of the facility.

6.3 The Risk Manager, Quality Management (QM) coordinates and manages the facility SMDA program in accordance with this memorandum and higher headquarters directives, and ensures the Commander and DCA (Deputy Commander for Admin) are aware of problems and obstacles which prevent compliance with pertinent directives. Maintains documentation on all device-related problems and tracked devices (except equipment).

6.4 Material Branch, Logistics Division is responsible for the maintenance and tracking of all life-sustaining or life-supporting (equipment) devices used within and outside the medical facility. For completing and submitting the SF 380, (Medical Materiel Complaints/Quality Improvement Report) to the Defense Personnel Support Center (DPSC/MOE) within 10 working days from the time the facility becomes aware of the event. Refer to paragraph 7.2 for equipment tracking procedures.

6.5 Clinical Engineering performs quality control and safeguard measures on any tracked equipment received for use within the medical facility, and investigates medical device problems in accordance with all pertinent directives. Works with the Risk Manager, Material Branch and Safety Officer on investigations of equipment/device-related problems and maintains records of tracked devices used outside the medical facility.

6.6 The Ambulatory Surgical Procedure Unit (ASPU) will track all medical devices, implanted or removed on a case by case basis, which are subject to tracking by the SMDA. Minimum tracking procedures are described in paragraph 7.2.

6.7 The Chief of each outpatient clinic and service is responsible for tracking medical devices implanted and removed on an outpatient basis in their clinic/service. Minimum tracking procedures are described in paragraph 7.2. The implantation and removal of devices listed in paragraph 5.2 falls outside the organizations scope of practice; however, our clinicians care for patients with these devices and thus assist in the monitoring and tracking process.

6.8 The Dental Service will track all medical devices (implanted or removed) on an outpatient basis within the Dental Service. Minimum tracking procedures are described in paragraph 7.2. The implantation and removal of dental devices listed in paragraph 5.2 falls outside the local DENTAC's scope of practice; however, dentists may care for patients with these devices and thus assist in the monitoring and tracking process.

6.9 When medical personnel(physicians, nurses, medical technicians, technologists, biomedical repair personnel) become aware of information that reasonably suggests that a reportable event has occurred, they are responsible for reporting that information to the Risk Manager using the procedures described in paragraph 7.1.

7. PROCEDURES.

7.1 Reporting. It is the responsibility of all health center personnel to report, within 24 hours, that in all probability a device has caused or contributed to a death, serious injury, or serious illness of a patient. For the purpose of reporting, the device does not have to be a device subject to SMDA tracking. It refers to any medical device. Refer to paragraph 9.1 for the definition of a device. Personnel will complete the DA Form 4106 at Appendix B and submit it to Clinical Engineering.

7.1.1 The DA Form 4106, Quality Assurance/Risk Management Document, is used to make written reports of Medical Device Related (MDR) events. Enter "MDR" in item 10 (other) on the incident statement to distinguish this event from other types of incidents and to facilitate locating MDR incidents. Once completed, the report is hand carried to the Risk Manager. The Risk Manager initiates the necessary further investigation and notifies other officials or offices, as appropriate. After duty hours and on weekends, incidents must be reported to the Primary Care Manager (PCM) on call, who is responsible for identifying a potential reportable event, initiating a DA Form 4106, and forwarding the DA Form 4106 to the Risk Manager the following duty day. The Primary Care Manager (PCM) on call will immediately notify the Deputy Commander Clinical Services and the Biomedical Engineer on-call person if the incident resulted in serious illness, serious injury or death.

7.1.2 The SF Form 380 is completed by Material Branch and forwarded to DPSC/MOE within 10 working days of when the facility becomes aware of a MDR event. A Type I Medical Materiel Complaint is completed for each MDR event which meets the criteria of paragraph 9.3. The DENTAC Commander will notify the MEDDAC Commander for MDR events pertaining to the Dental Service. See paragraph 9.3 for the definition of a Type I Medical Materiel Complaint.

7.2 Tracking. The manufacturer of a tracked device has primary responsibility for tracking the device from the manufacturer throughout distribution to the end user of the device. However, MTF personnel must ensure that manufacturers get the required information in a timely manner, and that a record of compliance with medical facility requirements is kept. The following local procedures will ensure medical facility compliance with SMDA tracking requirements:

7.2.1 Equipment. Upon receipt of each equipment item not intended for use outside the medical facility, Clinical Engineering (CE) and the Material Branch Quality Control (QC) officer will perform any quality control and safeguard measures required. Once completed, the manufacturers tracking form is completed and returned. The Defense Medical Logistics Standard Support (DMLSS) will be used to track equipment and maintain maintenance history. Information kept in the DMLSS database will include: device name, model/serial number, date received, location and ECRI UMDNS code. If and when equipment, subject to tracking, is used outside the facility and is assigned to a specific patient, additional information will be provided to the manufacturer and a record will be maintained by Property Management. This additional information will include: the name, address, telephone number, and social security number of the patient who receives the equipment; date that the device was provided to the patient; name, mailing address, and telephone number of the prescribing physician; name, mailing address, and telephone number of the physician assigned to follow-up with the patient, if different than the prescribing physician; and the date the equipment is returned.

7.2.2 Implantables subject to tracking by the SMDA. If the Surgical Suite, Outpatient Clinics/Services or Dental Activity implants or removes a tracked device, they must notify the manufacturer and risk manager as soon as possible, but not later than three working days. Usually, the manufacturer will provide a form with the tracked device, but if the form is not enclosed, the following information must be provided to the manufacturer and the risk manager:

7.2.2.1 Lot, batch, model or serial number of the device or other identifier necessary to track the device;

7.2.2.2 Name, address, telephone number, and social security number (if available) of the patient receiving the device,

7.2.2.3 Date that the device was provided to the patient.

7.2.2.4 Name, mailing address and telephone number of the prescribing physician and the physician assigned to follow-up with the patient if different from the prescribing physician.

7.2.3 Explantables subject to tracking by the SMDA. If applicable, the date that the device was removed and the name, mailing address, and telephone number of the removing physician; the date of the patient's death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise disposed of permanently.

7.3 Investigation of MDR Events. Clinical Engineering (CE) is responsible for the investigation of equipment problems that meet the criteria of paragraph 7.1. An Incident Investigation Checklist (Appendix A) is used to initiate a detailed investigation of the incident. As a minimum, the investigation includes:

7.3.1 Impounding the equipment, noting the position of all knobs and dials, noting any missing components or parts, and the overall condition of the equipment. The release of any equipment must be coordinated with the Risk Manager.

7.3.2 Interviews with involved personnel.

7.3.3 Identification of the supply items by lot number, date of manufacture, or any other means to specifically identify the exact item.

7.3.4 Review of maintenance history and test procedures.

8. EDUCATION. The Risk Management Office will ensure that the professional and provider staff are educated on the requirements of the SMDA.

9. DEFINITIONS.

9.1 Device - The Food, Drug, and Cosmetic Act (21 U.S.C. 321 (h)) defines a device as an instrument, apparatus, implement, machine, contrivance, implant, invitro reagent, or other similar or related article including any component, part, or accessory, which is:

9.1.1 Recognized in the official National Formulary or the United States Phannacopeia, or any supplement to them.

9.1.2 Intended for use in the diagnosis of disease or other conditions; or in the cure, mitigation, treatment, or prevention of disease in man or other animals or;

9.1.3 Intended to affect the structure or any function of the body of man or animals, and which does not achieve any of its principle intended purposes through chemical action within or on the body of man or animals, and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes. Examples include:

9.1.3.1 Anesthesia machines

9.1.3.2 Defibrillators

9.1.3.3 Pacemakers

9.1.3.4 Hemodialysis machines

9.1.3.5 Heart valve catheters

9.1.3.6 Thermometers

9.1.3.7 Patient restraints

9.1.3.8 Contact lenses

9.1.3.9 Hearing aids

9.1.3.10 Blood glucose monitors

9.1.3.11 X-Ray machines

9.1.3.12 Ventilators

9.1.3.13 Wheelchairs

9.1.3.14 Infusion pumps

9.2 Serious Injury or Illness:

9.2.1 Is life threatening;

9.2.2 Results in permanent impairment of a bodily function or permanent damage to a body structure;

9.2.3 Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

9.3 Type I Medical Materiel Complaint. A supply or equipment item that has been determined, by use or testing, to be harmful or defective to the extent that use has caused or may cause illness, injury or death. Immediate action is required to report such items and to remove them from using activities and serviceable inventories. Do not destroy suspect materiel prior to receiving disposition instructions.

The proponent of this publication is MCXJ-LO. Users are invited to send comments and suggested improvements on DA Form 2028 directly to USAMEDDAC, ATTN: Logistics Division, Medical Maintenance Branch, MCXJ-LO, Fort Huachuca, AZ 85613-7079.

FOR THE COMMANDER:

OFFICIAL:

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APPENDIX A
INCIDENT INVESTIGATION CHECKLIST

Biomedical equipment involved in or suspected of being involved in a device related incident requires proper preservation of evidence. Follow each step of the checklist below and provide as much information as possible.

Equipment Nomenclature ECN Number

Model Number Serial Number

1. IMPOUND THE EQUIPMENT! Report it to Clinical Engineering immediately. Include any accessories in use at the time of the incident. This includes, but is not limited to:

(1) Infusion sets
(2) Patient leads
(3) Electrodes (active & passive)
(4) Paddles
(5) Power cords
(6) Rebreathing circuits
(7) Temperature probes
(8) Charging stands
(9) Packaging material which shows lot number of disposables

2. DO NOT CHANGE ANY CONTROL SETTINGS! Record position of all knobs and dials of the equipment.

3. Interview all involved personnel including doctor, nurses, technicians, civilians, etc. Inquire about procedures performed, equipment set-up, and other facts available.

4. Identify all consumable supply items by lot number or date of manufacture.

5. How did the device respond when connected to the patient?

6. Was the patient on drug therapy or were there any related sensitivities?

7. Was the device used appropriately? Review operating instructions to verify.

8. Were control settings appropriate for the intended diagnostic or therapeutic procedure?

9. Were the consumable supplies or accessories designed for use with the affected device?

10. Clinical Engineering shall review equipment data file (maintenance history), and calibration and safety test procedures.

11. When was operator training accomplished and documented?

12. Were any facility utility problems identified before, during, or after the procedure; i.e., electrical, medical gas, water, suction; or heating, ventilation, and cooling (HVAC)?

QUALITY ASSURANCE/RISK MANAGEMENT DOCUMENT

For use of this form, see AR 40-68; the proponent agency is the OTSG.

Prepare this form according to instructions on the reverse side to document events which may have quality assurance/risk management implications involving patients, visitors or other persons.

1. Date of Event	2. Time of Event	3. Location	4. Age	5. Sex	6. ☐ INPATIENT ☐ OUTPATIENT ☐ EMERGENCY ROOM ☐ OTHER *(explain below)*	7. Attending Doctor

8. DIAGNOSIS(ES)	9. POST OP DAY

	10. TYPE OF OCCURRENCE/INCIDENT *(check one only)*		11. CONDITION AFTER OCCURRENCE	
	Adverse Drug Reaction *(see instructions)*		No Apparent Effect	Narrative *(optional)*:
	AMA/Walkout *(see instructions)*		Minor Injury or Effect	
	Blood Transfusion *(see instructions)*		Signficant Injury or Effect	
	Equipment		Death	
	Fall/Found on Floor *(Prescribed activity level:*)		Other *(explain in narrative box)*	
	Laboratory		12. ACTION TAKEN	YES / NO
	Medication *(to include IV)*		Doctor Notified	
	Pharmacy		Did Doctor see Patient	
	Practice/Procedure Variance *(staff)*		X-Rays ordered/taken	
	Property Loss or Damage		Reported to Supervisor/Department Chief	
	Other *(explain)*		Laboratory tests ordered/taken	
			Other *(explain in block 14)*	

13. WITNESSES ☐ NONE ☐ Yes *(complete boxes below)*

a. Name(s)	b. Duty Section or Home Address	c. Phone

14. DESCRIPTION OF EVENT *(Concise, Factual, Objective Statement)*

If more space is needed, use a continuation sheet.

15. Name, Grade, Title of Individual Completing Form *(print)*	16. Signature	17. Date of Report

18. PATIENT ID PLATE OR PRINTED NAME AND SSN	The information placed on this form is confidential and privileged IAW 10 U.S.C. 1102. **UNAUTHORIZED DISCLOSURE CARRIES A $3,000 FINE.** DO NOT FILE OR REFER TO THIS FORM IN PATIENT RECORD. REPORT EVENT TO SUPERVISOR/DEPARTMENT CHIEF IMMEDIATELY.
	FOR QA USE ONLY 19. Log Number _____ 20. Further analysis indicated NO ☐ YES ☐

DA FORM 4106, MAR 90 Previous edition is obsolete. USAPPC V2.00

INSTRUCTIONS: QUALITY ASSURANCE/RISK MANAGEMENT DOCUMENT

(See paragraph 3-5b, AR 40-68)

1. **PURPOSE:** To provide an effective method of documenting adverse occurrences/incidents to the MTF/DTF Commander. The reported data are used to monitor, evaluate, and improve the quality and safety of patient services delivered.

2. **SCOPE:** This form will be completed by any MTF/DTF employee who discovers an occurrence or incident. All occurrences and incidents should be reported as they happen. An occurrence is any accident or event not consistent with patient care that either did or could result in an injury to a patient. An incident is an event which does not necessarily involve patients, but may be the basis for a complaint, financial liability and/or disciplinary action.

3. **RESPONSIBILITY:** The individual who discovers the occurrence/incident will initiate the document.

4. **DIRECTIONS FOR COMPLETION:**
   a. 1 through 17. Complete all boxes. If "not applicable" or "none", please so state. If "other" is checked in any of the boxes, please explain in space provided in box 14.
   b. 8. List primary and secondary diagnoses as in patient's record and any other contributing diagnoses which may relate to the occurrence or incident.
   c. 9. List post operative day. If not applicable, state N/A.
   d. 10. For adverse drug reaction also complete Form FDA 1839, Adverse Reaction Report (Drugs and Biologics.) For blood transfusion also complete bottom portion of SF 518, Medical Record - Blood or Blood Component Transfusion. For AMA/Walkout also complete DA Form 5009-R, Release Against Medical Advice.
   e. 11. Check appropriate box. If other, explain in narrative box.
   f. 13. List any witnesses to event to include visitors or non-MTF personnel.
   g. 14. Provide an objective, concise and factual description of the event.
   h. 19 and 20. For QA/RM Office use only.

5. **ROUTING OF FORM:** The document should be forwarded through appropriate local channels but as a minimum should be completed and staffed through the Departments/Services concerned within 24 hours post completion and to the MTF/DTF, QA/RM Office, not later than 48 hours after the event.

(for local use)

Reverse of DA Form 4106